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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,076	07/24/2003	Andrea Venturelli	71067	4532
<div>24633 7590 11/30/2007 HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004</div>				
			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 11/30/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com

Office Action Summary

Application No.

10/626,076

Applicant(s)

VENTURELLI, ANDREA

Examiner

Bhisma Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/11/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The phrase "which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56(a)" should not be used in the declaration and should be replaced with "which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56".

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the main tube distal end having a lateral aperture delimiting a main tube edge and the proximal end of the distal tube being slantwise cut defining a distal tube outer edge. The specification also fails to disclose the method steps of providing a lateral opening on the main tube delimiting a main tube edge, cutting the distal tube proximal end with a slantwise and defining a distal tube outer edge, and extending the guide tube proximal end into the lateral aperture of the main tube and into the distal tube.

Claim Objections

3. Claims 1-22 are objected to because of the following informalities: In line 4 of claim 1, it is unclear if "said proximal end" refers to the proximal end of the main tube or the proximal end of the distal tube. It is unclear what is meant by "said distal proximal end" in line 4 of claim 18 and by "the distal tube main tube edge" in line 15 of claim 18. In lines 7-8 of claim 19, it appears that there is a grammatical error with the phrase "cutting the distal tube proximal end with a slantwise and defining a distal tube outer edge". It is also unclear what is meant by "the distal tube main tube edge" in line 17 of claim 19.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Lines 11-15 of claim 1 and lines 12-15 of claim 18 contain reference to the guide tube proximal end being flute cut defining a proximal guide tube edge and the flute cut being joined to at least a portion of the distal

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tube outer edge. Lines 12-17 of claim 19 contain reference to cutting the guide tube proximal end with flute cut defining a proximal guide tube edge of an opening on one side of the main tube and joining the flute cut to at least a portion of the distal tube outer edge and to at least a portion of the distal tube main tube edge. The language of "flute cut" is not described or defined in the specification, thus it is not clear what is being claimed with regards to the term "flute cut". The proximal end of the guide tube is not described or defined as being flute cut in the specification. Therefore, there is also no description of the flute cut being joined to at least a portion of the outer edge of the distal tube.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-17 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the main tube "having a lateral aperture delimiting a main tube edge". In lines 13-15 of claim 1, it is unclear if the "flute cut being joined to at least a portion of the distal tube outer edge and at least a portion of the main tube edge defining a side port in the catheter structure" is intended to indicate 1) that the flute cut is joined to at least a portion of the distal tube outer edge and to at least a portion of the main tube edge and that the flute cut defines a side port in the catheter structure or 2) that the flute cut is joined to at least a portion of the distal tube outer edge and it is the at least a portion of the main tube edge that defines a side port in the catheter structure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4-15, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith (U.S. Patent No. 5,156,594). In Figure 2, Keith shows a catheter structure or side port assembly having a main tube (22), a distal tube (82), a guide tube (80), and a balloon (38). In Figure 7, Keith shows the section of the catheter structure or side port assembly having a main tube (22C), a distal tube (82C), and a guide tube (80C). The main tube (22C) is formed from multiple tube sections (64C, 66C). The main tube has a lateral aperture (68, 119) delimiting a main tube edge. At least a portion (110 in Figure 2 and adjacent reference character 30C in Figure 7) of the proximal end of the distal tube is slantwise cut defining a distal tube outer edge. A portion of the guide tube (80C) extends into the distal tube (82C) and a portion of the guide tube (80C) adjacent to the proximal end (100C) of the distal tube is located adjacent to the distal end (shown at 66C) of the main tube. The guide tube (80C) has an opening at the proximal end (92C) of the guide tube on one side of the main tube (22C). A portion of the distal tube (82C) adjacent to the proximal end (100C) of the distal tube encloses both a portion of the distal end of the main tube and a portion of the guide tube adjacent to the guide tube proximal end. The proximal end of the guide tube extends into the lateral aperture (119) of the main tube and into the distal tube.

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The proximal end of the guide tube is flute cut and defines a proximal guide tube edge (32 in Figure 2 and 123 in Figure 7). The flute cut is joined to at least a portion of the distal tube outer edge and to at least a portion of the main tube edge defining a side port in the catheter structure. Keith also shows an inflation lumen (62C, 125, 104C) and a lumen (52C) for a guide thread. In Figure 2, a portion of the proximal end (100) of the distal tube (82) is flared. Keith teaches joining or sealing the ends of the different parts of the catheter structure by suitable means such as by a solder joint which is a form of heat sealing. The proximal ends of the guide tube and the distal tube are beveled at the lateral opening as seen in the figures. The multiple sections of the main tube have different material compositions, different thicknesses, and different rigidities and Keith teaches that the guide tube and the distal tube are formed from materials different than that of the main tube. In line 31-33 of column 7, Keith teaches that the guide tube and the distal tube may be formed of the same material or from materials different from one another. Keith discloses the method for manufacturing the catheter structure as claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claims 3, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Willard et al (U.S. Patent No. 6,309,379). Keith discloses the catheter structure substantially as claimed. Even though Keith shows a part of the distal end (72) of the main tube (22) which is deflected and inclined towards an inside of the main tube, Keith is silent on the proximal end of the guide tube resting on the outside of the inclined part of the main tube. It should be noted that Keith shows the edge of the lateral opening (119) of the main tube (22) in Figure 7 which can also be considered to be deflected and inclined towards an inside of the main tube. Willard et al disclose a balloon catheter structure in the same field of endeavor. In Figure 10, Willard et al show a proximal end of a guide tube (102) located in a lateral opening (50) of a main tube (10) where a part of the main tube is deflected and inclined toward an inside of the main tube and where the proximal end of the guide tube rests on the outside of the inclined part of the main tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to extend the guide tube of Keith such that the proximal end of the guide tube rests on the outside of the inclined part of the main tube as taught by Willard et al as Willard et al teach that it is well known to provide a portion of the guide tube that extends out of the lateral opening and rests on a part of the main tube so that a guide thread or guide wire can be more easily manipulated during a surgical procedure.

12. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Zarbatany et al (U.S. Patent No. 6,030,405). Keith discloses the method for manufacturing the catheter structure substantially as claimed. However,

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Keith is silent on the insertion of expanders into the distal end of the main tube and the proximal end of the guide tube during the heat-sealing operation. Zarbatany et al teach inserting expanders into the ends of tubes that will become a lumen for a guide thread or an inflation lumen and removing the expanders after use in the same field of endeavor of using heat-sealing to join the different sections of a catheter structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the lumens of Keith by using expanders as taught by Zarbatany et al as Zarbatany et al teach that it is well known to use expanders to form lumens when using heat-sealing to form a catheter structure.

Response to Arguments

13. Applicant's arguments with respect to the prior art rejections of claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

14. Applicant's arguments, see page 13, filed September 10 2007, with respect to the nonstatutory obviousness-type double patenting rejection of claims 1-18 have been fully considered and are persuasive. The nonstatutory obviousness-type double patenting rejection of claims 1-18 has been withdrawn.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

